MAR 1 4 2002

K020160

510(k) Summary

510(k) Submission Information:

Device Manufacturer:	Dade MicroScan Inc.
Contact name:	Cynthia Van Duker, Regulatory Affairs Manager
Fax:	916-374-3144
Date prepared:	January 16, 2002
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan® Dried Gram-Positive MIC/Combo Panels
Intended Use:	To determine antimicrobial agent susceptibility
510(k) Notification:	New QC range - Ampicillin
Predicate device:	MicroScan Dried Gram Positive MIC/Combo Panels

510(k) Summary:

MicroScan® Dried Gram-Positive MIC/Combo Panels are designed for use in determining quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative Gram-Positive cocci.

The antimicrobial susceptibility tests are miniaturizations of the broth dilution susceptibility test that have been diluted in broth and dehydrated. Various antimicrobial agents are diluted in broth to concentrations bridging the range of clinical interest. Panels are rehydrated with water, after inoculation with a standardized suspension of the organism. After incubation in a non-CO_2 incubator for 16-20 hours, the minimum inhibitory concentration (MIC) for the test organism is read by determining the lowest antimicrobial concentration showing inhibition of growth.

The proposed MicroScan® Dried Gram-Positive MIC/Combo Panel demonstrated substantially equivalent performance when compared with an NCCLS frozen Reference Panel, as defined in the FDA DRAFT document "Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices", dated March 8, 2000. The Premarket Notification (510[k]) presents data in support of a revised Quality Control range for Ampicillin with *S. aureus* ATCC 29213 on the MicroScan® Dried Gram-Positive MIC/Combo Panel.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 4 2002

Ms. Cynthia Van Duker
Regulatory Affairs Manager
Dade Behring Inc.
1584 Enterprise Boulevard
West Sacramento, CA 95691

Re: k020160
Trade/Device Name: MicroScan® Dried Gram-Positive MIC/Combo Panels with Ampicillin (0.008-128 mcg/ml)
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: LTT, JWY
Dated: January 16, 2002
Received: January 17, 2002

Dear Ms. Van Duker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K020160

Device Name: MicroScan® Dried Gram-Positive MIC/Combo Panels with Ampicillin (0.008 - 128 mcg/ml)

Indications For Use:

The MicroScan® Dried Gram-Positive MIC/Combo Panel is used to determine quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative Gram-Positive cocci. After inoculation, panels are incubated for 16 – 20 hours at 35°C +/- 1°C in a non-CO2 incubator, and read either visually or with MicroScan instrumentation, according to the Package Insert.

This particular submission is for a revised QC range of ≥ 0.5 mcg/ml for *S. aureus* ATCC #29213 with Ampicillin.

The Gram-Positive organisms which may be used for Ampicillin susceptibility testing in this panel are:

Staphylococcus aureus (beta-lactamase and non-beta-lactamase producing)
Staphylococcus epidermidis (beta-lactamase and non-beta-lactamase producing)
Staphyloccus saprophyticus (beta-lactamase and non-beta-lactamase producing)
Streptococcus faecalis (Enterococcus)
Streptococcus pyogenes

The MicroScan® Dried Gram-Positive MIC/Combo Panels with Ampicillin are not intended for use with *Streptococcus pneumoniae* and viridans streptococci.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Freddie Lee Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K02 0160

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____.

(Optional Format 1-2-96)